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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,394	09/10/2003	Patrick Mailliet	ST99049G1 US DIV	2263
5487	7590	10/17/2007		
ANDREA Q. RYAN SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER JARRELL, NOBLE E	
			ART UNIT 1624	PAPER NUMBER
			NOTIFICATION DATE 10/17/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## Office Action Summary

Application No.

10/658,394

Applicant(s)

MAILLIET ET AL.

Examiner

Noble Jarrell

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1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22,24-27 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25,26 and 36 is/are allowed.
- 6) ☒ Claim(s) 22,24,27 and 31-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Current Status of 10 / 658394**

1. The amendment filed 9/14/2007 is acknowledged and all of the arguments have been fully considered.
2. The rejection under 112 1<sup>st</sup> paragraph regarding the treatment of all forms of cancer has been overcome by the amendment filed 9/14/2007.
3. The rejection under 112 1<sup>st</sup> paragraph regarding compositions of compounds of claim 1 with other anticancer agents has not been overcome. Applicants have still not shown that stable compositions can be formed with compounds of formula I and anticancer agents. Applicants have imported anticancer agents from the specification into claim 34 in order to clear what was meant by "analogues and derivatives". However, this does not overcome the rejection because applicants have not shown that compounds of formula I can be mixed with other anticancer agents in stable compositions. Therefore, claims 31-35 are still rejected.
4. The rejection under 112 1<sup>st</sup> paragraph regarding a method of using compounds of formula I with radiation has been overcome by the amendment filed 9/14/2007.

### ***Specification***

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title is not descriptive because "chemical derivatives" is unclear. That term can mean *any* derivative of *any* chemical.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. (*Journal of Medicinal Chemistry*, **1971**, 14(6), 532-535) in view of Patani and LaVoie (*Chemical Reviews*, **1996**, 96, 3147-3176) and Evans et al. (*Journal of Medicinal Chemistry*, **1967**, 10, 428-31).

Singh et al. teach structure 22 of table 1, which does not anticipate formula I because both quinoline rings each have one chlorine attached to them (chlorine is not a valid substituent for the quinoline rings according to claim 22).

Patani and LaVoie teach on page 3153, table 12, that a Cl atom is a bioisosteric equivalent group for H. Patani and LaVoie explain bioisosterism for this example in the inhibition of thymidylate synthase. Table 12 shows that the chloro derivative had better activity than the unsubstituted compound. Patani and LaVoie do not teach compounds of formula I.

Evans et al. teach the formation of pharmaceutically acceptable composition for use in the testing of anti-inflammatory activity of compounds in Sprague-Dawley rats. Tested compounds were mixed with carageenan and saline for injection, and then 0.1 mL of the solution was injected into the plantar surface of the right hind foot of each rat. Since this composition was given orally to rats, the composition can be considered pharmaceutically acceptable. Evans does not teach compounds of claim 22.

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The rationale for combining the Singh and Evans references together arises from the fact that Singh et al. used the same composition in their paper (albeit their own compounds, not Evans' compounds), because it is stated: "All compounds except 20 were tested for their antimalarial activity against *Plasmodium berghei* in mice by Dr. L. Rane according to the procedure already published." (page 532, column 2, section "Biological tests") Therefore, Singh et al. made a composition of compound 22, carageenan, and saline, which was given to rats. Thus claim 27 is rendered unobvious over the teachings of Singh et al. in view of Evans et al.

The rationale for combining the Singh and Patani and LaVoie references together arises from the fact it would be obvious to try a chlorinated (instead of unsubstituted) quinoline for antitelomerase activity. Patani and LaVoie teach that a chlorine atom is a bioisosteric equivalent for H, and it would be obvious to one of ordinary skill in the art to see if this compound can inhibit telomerase. After all, the compound is being used as a drug and Patani and LaVoie discuss the relationship of bioisosterism to drug design.

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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10. Claims 22, 24, 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5, and 9 of copending Application No. 10/993637. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain overlapping subject matter. In addition, example 15 (page 54) of the instant application can be embraced by both sets of claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Allowable Subject Matter***

11. Claims 25, 26, and 36 are allowed.

12. The following is a statement of reasons for the indication of allowable subject matter: Singh et al report the closest prior art., who use the compounds of claim 22 for antimalarial use, not antitelomerase activity.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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